

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

THE UNITED STATES OF AMERICA, <i>et al.</i> ,	:	
<i>ex rel.</i> CATHERINE A. BROWN and	:	
BERNARD G. VEZEAU	:	
	:	CIVIL ACTION
v.	:	
	:	NO. 05-6795
PFIZER, INC.	:	

MEMORANDUM

SURRICK, J.

JUNE 22, 2017

Presently before the Court is Defendant's Motion to Certify Questions for Interlocutory Review And For Stay. (ECF No. 126.) For the following reasons, Defendant's Motion will be granted.

I. BACKGROUND

Eleven years ago, Relators filed this lawsuit against Defendant Pfizer under the False Claims Act ("FCA") based on allegations that Defendant submitted misleading information to the Food and Drug Administration ("FDA"), and concealed critical information in order to gain approval of its antifungal drug, Vfend. A full review of the facts in this matter appears in our previous Memoranda addressing Defendant's First and Second Motions to Dismiss, dated February 29, 2016 and April 12, 2017, respectively. (ECF Nos. 94, 122.)

A. Procedural History

On December 29, 2005, Relators filed a *qui tam* Complaint on behalf of the United States under seal, pursuant to the FCA, 31 U.S.C. § 3729 et seq. (ECF No. 1.) Nearly four years later, on December 1, 2009, Relators filed an Amended Complaint. (ECF No. 19.) The case remained under seal for six years while the United States decided whether to intervene. Ultimately, the

United States declined to intervene, and on November 28, 2011, the Amended Complaint was unsealed. (ECF No. 32.) Defendant filed a motion to dismiss Relators' Amended Complaint, which we granted in part and denied in part. Relators then filed a Second Amended Complaint. (SAC, ECF No. 98.) Defendant filed a motion to dismiss Relators' SAC, which we denied. Defendant now seeks interlocutory review of our April 12, 2017 Memorandum and Order.

B. Relevant Facts

Defendant seeks certification of the April 12th Order, which denied Defendant's Second Motion to Dismiss Relators' SAC. Relators' SAC alleges that Defendant knowingly caused to be presented false or fraudulent claims for payments, and knowingly entered into conspiracies with paid "speakers," medical marketing firms, "experts," and other third parties for the purpose of defrauding the United States Government. (SAC ¶¶ 204-20.) Defendant made several arguments in its Second Motion to Dismiss. Three of these arguments are relevant for the purposes of addressing the instant Motion. They are: (1) that the Court lacked subject matter jurisdiction over portions of Relators' SAC; (2) that Defendant's off-label use of Vfend on neutropenic patients and for empiric therapy is covered by Medicare; and (3) that Relators have failed to satisfy the materiality requirement of the FCA because the Government continued to pay for Vfend despite Relators' allegations in 2005. In the Memorandum and Order of April 12th, after a full analysis, we concluded that: (1) Relators were permitted to file an amended complaint in order to cure a first-to-file defect; (2) 42 U.S.C. § 1395x(t)(2)(A) applied to Vfend, an antifungal drug; and (3) the Government's continued payments of Vfend were insufficient to establish that Relators' claims failed for lack of materiality.

Defendant's instant Motion requests that this Court certify three questions for interlocutory review:

1. Is it possible for allegations to satisfy the FCA’s demanding materiality requirement when the government learned about the allegations more than a decade ago, conducted a multi-year investigation, and continues to pay the relevant claims?

2. If a relator “brings a related action” in violation of the FCA’s first-to-file rule, can the relator cure this defect merely by filing an amended complaint after the earlier-filed lawsuit is no longer “pending?”

3. Does 42 U.S.C. § 1395x(t)(2)(B) apply to Vfend even though it is not “used in any anticancer chemotherapeutic regimen?”

II. LEGAL STANDARD

Generally, an order denying a motion to dismiss is not immediately appealable because it is not a final judgment. *See In re Chocolate Confectionary Antitrust Litig.*, 607 F. Supp. 2d 701, 704 (M.D. Pa. 2009) (“Denials of motions to dismiss are not final orders, and a losing party may not ordinarily pursue an immediate appeal from them.”). However, district courts may certify a non-final order for interlocutory appeal under 28 U.S.C. § 1292(b). *Id.* To certify a non-final order for interlocutory appeal, “[t]he order must (1) involve a ‘controlling question of law,’ (2) offer ‘substantial ground for difference of opinion’ as to its correctness, and (3) if appealed immediately, ‘materially advance the ultimate termination of the litigation.’” *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 754 (3d Cir. 1974) (quoting 28 U.S.C. § 1292(b)). However, “[t]he certification procedure is not mandatory; indeed, permission to appeal is wholly within the discretion of the courts, even if the criteria are present.” *Bachowski v. Usery*, 545 F.2d 363, 368 (3d Cir. 1976).

The decision to certify an order for interlocutory review is only appropriate in “exceptional circumstances and we should be mindful of the strong policy against piecemeal appeals when exercising our discretion.” *U.S. ex rel. Nevyas v. Allergan, Inc.*, No. 09-432, 2015 WL 4064629, at *2 (E.D. Pa. July 2, 2015) (citation and internal quotation marks omitted). “The

Third Circuit has held that certification is to be used in exceptional cases where an immediate appeal would avoid protracted and expensive litigation.” *Zygmuntowicz v. Hosp. Investments, Inc.*, 828 F. Supp. 346, 353 (E.D. Pa. 1993) (internal citations omitted). “The party seeking interlocutory review has the burden of persuading the district court that exceptional circumstances exist that justify a departure from the basic policy of postponing appellate review until after the entry of final judgment.” *Premick v. Dick’s Sporting Goods, Inc.*, No. 06-0530, 2007 WL 588992, at *2 (W.D. Pa. Feb. 20, 2007) (citation omitted).

III. DISCUSSION

A. Three-Part Test

As noted above, a non-final order may be certified for interlocutory appeal if it: (1) involves a “controlling question of law,” (2) for which there is “substantial ground for difference of opinion,” and (3) which may “materially advance the ultimate termination of the litigation” if appealed immediately. *Katz*, 496 F.2d at 754. “Before an order can be certified all three of the factors identified in § 1292(b) must be met; the importance of a single factor, standing alone, cannot be determinative.” *Piazza v. Major League Baseball*, 836 F. Supp. 269, 270 (E.D. Pa. 1993) (citing *Katz*, 496 F.2d at 754). We address each factor in turn.

1. Controlling Question of Law

In our April 12th Order, we denied Defendant’s Motion to Dismiss Relators’ SAC. “An order involves a controlling question of law if either (1) an incorrect disposition would constitute reversible error if presented on final appeal or (2) the question is ‘serious to the conduct of the litigation either practically or legally.’” *In re Chocolate Confectionary Antitrust Litig.*, 607 F. Supp. 2d at 705 (quoting *Katz*, 496 F.2d at 755).

If the Third Circuit were to disagree with our determination that: (1) Relators were permitted to file an amended complaint in order to cure a first-to-file defect; (2) 42 U.S.C. § 1395x(t)(2)(A) applied to Vfend, an antifungal drug; or (3) the Government's continued payments for Vfend were insufficient to establish that Relators' claims failed for lack of materiality, the Order denying Defendant's Second Motion to Dismiss would be reversed. Consequently, Relators' prophylactic and pediatric claims would be barred by either the first-to-file rule or the statute of limitations; Relators' empiric therapy claims would be dismissed; or Relators' claims would fail because they do not meet the materiality requirement necessary to establish a claim under the FCA. Accordingly, our Order presents controlling questions of law.

2. *Substantial Ground for Difference of Opinion*

Defendant's instant Motion requests that we certify three separate questions for interlocutory appeal, each of which raises a different legal question. In order for a substantial ground for difference of opinion to exist, Defendant must prove that "there is genuine doubt or conflicting precedent as to the correct legal standard applied in the orders at issue." *Bush*, 629 F. Supp. 2d at 475 (citation omitted). "The difference of opinion must involve one or more difficult and pivotal questions of law not settled by controlling authority and the party has the burden of showing the different courts have issued conflicting and contradictory opinions when interpreting a particular question of law." *Glover v. Udren*, No. 08-990, 2013 WL 3072377, at *3 (E.D. Pa. June 18, 2013) (internal quotation marks and citations omitted); *see also In re Chocolate Confectionary Antitrust Litig.*, 607 F. Supp. 2d at 706 ("The existence of conflicting judicial opinions provides support for certification of an appeal, as does a lack of binding precedent."). However, a matter of first impression is not, in and of itself, sufficient to support certification for interlocutory appeal. *Cuttic v. Crozer-Chester Med. Ctr.*, 806 F. Supp. 2d 796,

805 (E.D. Pa. 2011); *see also Shaup v. Frederickson*, No. 97-7260, 1998 WL 800321, at *3 (E.D. Pa. Nov. 17, 1998) (“If questions of first impression alone were sufficient to warrant certification for an immediate appeal, our Court of Appeals would be besieged with piecemeal interlocutory appeals.”).

i. First-to-File

Defendant argues that courts have ruled that an amended complaint does not cure the first-to-file bar under the FCA. As we noted in our Memorandum, we agree that some courts have held that filing an amended complaint does not cure a first-to-file defect. *See United States ex rel. Brown v. Pfizer, Inc.*, No. 05-6795, 2017 WL 1344365, at *3 n.1 (E.D. Pa. Apr. 12, 2017). While the First Circuit and several district courts have held that a relator may file an amended complaint in order to cure a first-to-file defect, other district courts have reached the opposite conclusion. *See, e.g., United States v. Medco Health Sols., Inc.*, No. 11-684, 2017 WL 63006, at *12 (D. Del. Jan. 5, 2017); *U.S. ex rel. Carter v. Halliburton Co.*, 144 F. Supp. 3d 869, 880 (E.D. Va. 2015). The lack of controlling authority from the Supreme Court or Third Circuit, combined with the varying conclusions reached by the First Circuit and district courts, demonstrates that there is substantial ground for a difference of opinion as to whether a relator can file an amended complaint to cure a first-to-file defect.

ii. Materiality

Defendant argues that courts have ruled that a relator cannot satisfy the FCA’s materiality requirement if the Government reimburses a defendant despite existing allegations of fraud. In *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2003 (2016), the Supreme Court held that “if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not

material.” As we noted in our previous Memorandum, there are competing theories with regard to what defines “actual knowledge.” The Supreme Court left open the question of what constitutes “actual knowledge,” and lower courts have reached varying conclusions on the matter. On remand from the Supreme Court, the First Circuit in *Escobar* stated that “mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance.” *Universal Health Servs., Inc. v. United States*, 842 F.3d 103, 112 (1st Cir. 2016). Conversely, only one month later, the First Circuit in *D’Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) noted that “the fact that CMS [did] not den[y] reimbursement for [the defendant] in the wake of [the relator’s] allegations casts serious doubt on the materiality of the fraudulent representations that [the relator] allege[d].” The lack of controlling authority from the Supreme Court or Third Circuit, combined with the conflicting conclusions in the First Circuit, demonstrates a substantial ground for difference of opinion as to whether allegations of noncompliance demonstrates “actual knowledge” of the noncompliance.

iii. Medicare Claims

Defendant argues that the statutory provision that we applied to Relators’ Medicare claims—42 U.S.C. § 1395x(t)(2)(B)—does not apply to Vfend. In our prior Memoranda addressing Defendant’s First and Second Motions to Dismiss, we held that the statutory provision was not limited to anticancer drugs, and that it applied to antifungal drugs such as Vfend. Defendant has not presented any controlling authority on this matter. However, Defendant has cited two district court cases, both of which apply different statutory language. *See Broome v. Burwell*, No. 14-01248, 2015 WL 1526532, at *4 (D. Or. Apr. 1, 2015); *Nievod v. Sebellius*, No. 11-4134, 2013 WL 503089, at *2 (N.D. Cal. Feb. 8, 2013). In light of the lack of binding precedent, we find that there exists a substantial ground for a difference of opinion.

3. *Materially Advance Termination of the Litigation*

In considering whether an appeal would materially advance the ultimate termination of litigation, “courts have focused on whether an appeal would (1) eliminate the need for trial, (2) eliminate complex issues so as to simplify the trial, or (3) eliminate issues to make discovery easier and less costly.” *United States v. Exide Corp.*, No. 00-cv-3057, 2002 WL 992817, at *2 (E.D. Pa. May 15, 2002); *see also Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 553, 600 (E.D. Pa. 2008) (considering “whether the need for trial would be eliminated [and] whether the trial would be simplified by the elimination of complex issues”).

In determining whether certification would materially advance the termination of the litigation, courts often consider whether the parties have initiated discovery. “Certification is more likely to materially advance the litigation where the appeal occurs early in the litigation, before extensive discovery has taken place and a trial date has been set.” *Katz v. Live Nation, Inc.*, No. 09-3740, 2010 WL 3522792, at *3 (D.N.J. Sept. 2, 2010); *see also UnitedHealth Grp. Inc. v. MacElree Harvey, Ltd.*, No. 16-1026, 2016 WL 5239675, at *3 (E.D. Pa. Sept. 21, 2016) (holding that immediate appeal would materially advance termination of the litigation because the case was “early in its life-cycle” and “[s]ubstantial discovery ha[d] not yet occurred”); *In re Chocolate Confectionary Antitrust Litig.*, 607 F. Supp. 2d at 707 (“Cases in which discovery has closed are generally inappropriate for interlocutory appeal because they are rapidly approaching conclusion under their own momentum.”) (citation omitted); *Aluminium Bahrain B.S.C. v. Dahdaleh*, No. 08-299, 2012 WL 5305169, at *3 (W.D. Pa. Oct. 25, 2012) (holding that immediate appeal would materially advance termination of the litigation because discovery “promise[d] to be lengthy and complex”). Here, discovery has not yet commenced, and a trial date has not been set. Given the complexity of this case, we anticipate that discovery will be

extensive. “Appellate review of the motions to dismiss could eliminate the need for this period of prolonged and costly discovery,” or alternatively, it could “validate these significant expenditures.” *In re Chocolate Confectionary Antitrust Litig.*, 607 F. Supp. 2d at 708. If the Third Circuit rules in Defendant’s favor with regard to all three issues, we could avoid wasting significant time and resources on what may be needless discovery in this eleven year-old case.

In considering whether an appeal would materially advance the ultimate termination of litigation, “[i]t is not required that a reversal of the Court’s Order would end the litigation.” *Domestic Drywall*, No. 13-2437, 2016 WL 2941114, at *4 (E.D. Pa. May 20, 2016) (citing *Katz*, 496 F.2d at 755). Courts have ruled that if “resolution of the issue could clarify at least one complex issue,” then the moving party has satisfied their burden of proving that certification would materially advance the ultimate termination of the litigation. *Id.*; *see also UnitedHealth Grp.*, 2016 WL 5239675, at *3 (certifying the case for interlocutory appeal because “the vast majority of this case [could] necessarily be dismissed”); *Patrick v. Dell Fin. Servs.*, 366 B.R. 378, 387 (M.D. Pa. 2007) (certifying the case for interlocutory review because “[w]hile a reversal of [the order] does not, by itself, terminate th[e] litigation, it would resolve a large portion of the litigation without wasting the scarce resources of [the court] and the parties”); *Courtney v. La Salle Univ.*, No. 92-3838, 1996 WL 363910, at *2 (E.D. Pa. June 28, 1996) (finding that certification could materially advance the ultimate termination of the litigation because it could “eliminate a key issue” for trial); *Nationwide Life Ins. Co. v. Commonwealth Land Title Ins. Co.*, No. 05-281, 2011 WL 1044864, at *4 (E.D. Pa. Mar. 23, 2011) (same). Here, if the Third Circuit finds that: (1) Relators’ SAC does not cure the first-to-file defect; (2) Relators’ SAC does not satisfy the FCA’s materiality requirement; or (3) 42 U.S.C. § 1395(t)(2)(B) does not apply to Vfend, then—based on Relators’ Complaint—the vast majority

of Relators' claims will be eliminated, potentially leaving only Relators' kickback claims. Accordingly, we conclude that a brief delay for appellate review of the April 12th Memorandum and Order could clarify the law in this area, and materially advance the ultimate termination of this litigation.

Notwithstanding the fact that this case is eleven years old, because the April 12th Memorandum and Order involve controlling questions of law for which there is "substantial ground for difference of opinion," and "an immediate appeal from the [O]rder may materially advance the ultimate termination of the litigation," we are compelled to conclude that it is appropriate to certify Defendant's proposed questions for interlocutory review. 28 U.S.C. § 1292(b).

B. Stay Proceedings

Defendant also requests that we stay the proceedings pending the resolution of the interlocutory appeal. "Each court has the inherent power to control its own docket to promote fair and efficient adjudication." *New Jersey Prot. & Advocacy, Inc. v. New Jersey Dep't of Educ.*, No. 07-2978, 2008 WL 4692345, at *5 (D.N.J. Oct. 8, 2008) (citing *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936)). Here, we certify our April 12th Order for appellate review since resolution of the three issues may eliminate complex issues and make discovery easier and less costly for the parties. A stay is appropriate in this action in order to facilitate these objectives. Accordingly, we will stay this action pending resolution of the interlocutory appeal of the April 12th Order.

IV. CONCLUSION

For the foregoing reasons, Defendant's Motion to Certify Questions for Interlocutory Review and for Stay will be granted.

An appropriate Order follows.

BY THE COURT:

A handwritten signature in dark ink, appearing to read 'R. Surrick', is written over a light gray rectangular background.

R. BARCLAY SURRICK, J.